DEPT. OF HEALTH, AND HUMAN SERVICES PUBLIC HEALTH SERVICE	APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11 (c) FOR A		Form Approved No. 57R0068		
FOOD AND DRUG ADMINISTRATION	LASER LIGHT	SHOW, DISPLAY EVICE	DOCKET NUMBER		
NOTE: No laser light show or display device or use without the approval of	may vary from compliance w	ith 21 CFR 1040.11(c) in de	2 *60 181 - 7 8.9 *18		
INSTRUCTIONS					
Check all applicable boxes and type or print Submit an original and four (4) copies	me requested information.	Administratio Room 4 4. Enter Docket Num	-65, 5600 Fishers Lane, Rockville, MD 20857		
1. NAME OF COMPANY					
Creative Artists Productions					
2. ADDRESS OF COMPANY (include ZIP Code)	A41 OA 202				
240 Renaissance Parkway #201	, Atlanta, GA 303	50 8 Albania - Albania Albania - Al			
3. NAME OF RESPONSIBLE PERSON	4. TELEPHONE NO. (Ir	nclude area code)	1 5. DATE OF SUBMISSION		
Martin Zbosnic	404-874-7714		December 29, 1999		
6. The applicant requests the variance to be in eff	ect for a period of 2_years	from the date of issue. (In	general the Agency will approve		
a variance for only two years. If a longer period			the application.)		
	RODUCT DESCRIPT	ION AND USE			
a. LIST NAME AND MODEL NUMBER(S)					
MOBOLAZER ML10-200, ML10-30					
 PRODUCT FOR WHICH A VARIANCE IS REQ A LASER DISPLAY DEVICE 	DESTED	f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION x MORE THAN 15 DAYS			
A PROJECTOR FOR A LASER LIGHT SHOW		X MORE THAN 5 BUT NOT MORE THAN 15 DAYS			
X A LASER LIGHT SHOW		x LESS THAN 5 DAYS			
OTHER (Specify)					
		g. TOUR IS INTENDED			
C. X PROJECTORS ARE INTENDED FOR SALE, LEASE OR LOAN TO			MORE THAN 6 MONTHS		
OTHER LASER LIGHT SHOW PRODUCERS 1. PRODUCT IS INTENDED FOR USE IN A		1-6 MONTHS LESS THAN 1 MONTH			
x PLANETARIUM OR OTHER DOME PROJEC	TION STRUCTURE	OTHER (Specify)			
X THEATER X DISCOTHEQUE OR NIGHT CLUB					
x PAVILION		h. PRODUCT UTILIZES	THE FOLLOWING LASER EFFECTS		
X INDOOR ARENA		x FRONT SCREEN F	x FRONT SCREEN PROJECTIONS		
x OUTDOOR ARENA		X REAR SCREEN PROJECTIONS			
X MUSEUM X OUTDOOR ENCLOSED AREA		HOLOGRAPHIC DI	SPLAYS CTIONS (multiple channels or diffraction effects)		
OTHER (Specify)		_ AUDIENCE SCANNING			
		X REFLECTIONS FROM STATIONARY MIRROR(S) OR			
- DEODUCT IS INTENDED TO BE USED		MIRRORED SURF			
e. PRODUCT IS INTENDED TO BE USED <u>x</u> AT ONLY ONE (fixed) LOCATION		X STATIONARY IRRADIATION OF ROTATING MIRROR BALL(S) OR OTHER MIRRORED SHAPES			
X AT A VARIETY OF (tour) LOCATIONS	T A VARIETY OF (tour) LOCATIONS X SCANNING IRRADIATION OF ROTATING				
OTHER (Specify)		x FIBER OPTIC PRO	JECTIONS OTHER SCATTERING EFFECTS		
		OTHER (Specify)	THE SCATTERING CITEOTS		
8.	LASER R	ADIATION LEVELS	o na nativa y ladi antin'i ilay mpaka arah, arah dagasar ji kantana kasar ka di santasa da kantana da matan da		
LASER MEDIUM(Ar, He-Ne, etc.)	WAVELENG	THS (nm)	PEAK POWER (Watts)		
Argon	455-514 nm	· · · · · · · · · · · · · · · · · · ·	2 Watts		
Argon / Krypton	455-670 nm		500 mW		
NHWAC.	522 nm		5 Motte		

LASER MEDIUM(Ar, He-Ne, etc.)	WAVELENGTHS (nm)	PEAK POWER (Watts) 2 Watts 500 mW 5 Watts	
Argon	455-514 nm		
Argon / Krypton	455-670 nm		
Nd/YAG	532 nm		

AMPLITUDE

Scanned: D.C. to 500 Hz

Amplitude: 60 deg., peak to peak

10. REASON FOR REQUESTING VARIANCE

X COMPLIANCE WITH THE LIMITS OF 21 CFR 1040.11(c) WOULD RESTRICT THE INTENDED USE OF THE PRODUCT BECAUSE
COMPLIANCE WOULD LIMIT THE OUTPUT POWER TO THE EXTENT THAT THE DESIRED EFFECTS WOULD NOT BE
SUFFICIENTLY VISIBLE

__ OTHER OR ADDITIONAL EXPLANATION (Specify)

- 11, MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARD X IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11 (c) IN THAT THE ACCESSIBLE EMISSION LEVEL WOULD EXCEED THE ACCESSIBLE EMISSION LIMITS OF CLASS I OR CLASS II
 - IT IS PROPOSED TO DEVIATE FROM THE PROVISION OF 21 CFR 1040.11 (c) AS FOLLOWS:
- 12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION
 - X LASER LIGHT SHOWS AND DISPLAYS ARE ACCEPTED POPULAR MEDIA IN ENTERTAINMENT AND THE ARTS, USE OF POWER LEVELS IN EXCESS OF THE LIMITS IMPOSED BY 21 CFR 1040.11 (c) IS NECESSARY TO ACHIEVE THE REQUIRED EFFECTS IN THESE MEDIA.
 - OTHER OR ADDITIONAL ADVANTAGES (describe and explain)
- 13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. (Check as many boxes as apply. In item 14 "Remarks", justify any boxes not checked, using additional sheets as necessary. State any other means of radiation protection that will be used.)
- a. X ALL LASER PRODUCTS, SYSTEMS AND PROJECTORS WILL BE CERTIFIED TO COMPLY WITH 21 CFR 1040.10 AND THE CONDITIONS OF THIS VARIANCE AND WILL BE REPORTED AS REQUIRED BY 24 CFR 1002.10 AND 1002.12 USING THE REPORTING GUIDES PRO-VIDED FOR SUCH PURPOSE. THESE ACTIONS WILL BE ACCOMPLISHED PRIOR TO ANY INTRODUCTION INTO COMMERCE.
- b. X EFFECTS NOT SPECIFICALLY INDICATED IN THIS VARIANCE APPLICATION WILL NOT BE PERFORMED, NO OTHER EFFECTS WILL BE ADDED UNTIL AN AMENDMENT TO THE VARIANCE HAS BEEN OBTAINED AND THE REQUIRED REPORTS OR SUPPLEMENTS, AS APPLICABLE, HAVE BEEN SUBMITTED.
- c. X SCANNING, PROJECTION, OR REFLECTION OF LASER AND COLLATERAL RADIATION (LIGHT SHOW RADIATION) INTO AUDIENCE OR OTHER ACCESSIBLE UNCONTROLLED AREAS WILL NOT BE PERMITTED EXCEPT FOR DIFFUSE REFLECTIONS PRODUCED BY THE ATMOSPHERE, ADDED ATMOSPHERIC SCATTERING MEDIA, AND TARGET SCREENS.
- d. X LASER RADIATION LEVELS IN EXCESS OF THE LIMITS OF CLASS I WILL NOT BE PERMITTED AT ANY POINT LESS THAN 3.0 METERS ABOVE ANY SURFACE UPON WHICH PERSONS OTHER THAN OPERATORS, PERFORMERS, OR EMPLOYEES ARE PERMITTED TO OR 2.5 METERS BELOW OR IN LATERAL SEPARATION FROM ANY PLACE WHERE SUCH PERSONS ARE PERMITTED TO BE. OPERATORS, PERFORMERS, AND EMPLOYEES WILL NOT BE REQUIRED OR ALLOWED TO VIEW RADIATION ABOVE THE LIMITS OF CLASS LOR BE EXPOSED TO RADIATION ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11 (c).
- e. X ANY PRODUCT WHICH RELIES ON SCANNING TO MEET ACCESS, EXPOSURE, OR PRODUCT CLASS LIMITS WILL INCORPORATE A SCANNING SAFEGUARD SYSTEM WHICH DIRECTLY SENSES SCANNER MOTION AND WHICH WILL REACT FAST ENOUGH TO PRECLUDE EXCEEDING THE APPLICABLE LIMIT.
- f. X ALL LASER LIGHT SHOWS SHALL BE UNDER THE DIRECT AN PERSONAL CONTROL OF TRAINED, COMPETENT OPERATOR(S). THE OPERATOR(S) WILL:
 - (1) IMMEDIATELY TERMINATE THE EMISSION OF LIGHT SHOW RADIATION IN THE EVENT OF ANY UNSAFE CONDITION;
 - (2) BE LOCATED WHERE ALL BEAM PATHS CAN BE DIRECTLY OBSERVED AT ALL TIMES; AND
 - (3) BE AN EMPLOYEE OF THE VARIANCE HOLDER WHO WILL BE RESPONSIBLE FOR THE TRAINING AND CONDUCT OF OPERATOR
- g., X THE MAXIMUM LASER PROJECTOR OUTPUT POWER WILL NOT EXCEED THE LEVEL REQUIRED TO OBTAIN THE INTENDED EFFECTS.
- h. X THE PROJECTION SYSTEM (I.E., THE PROJECTOR AND ALL OTHER COMPONENTS USED TO PRODUCE THE LIGHTING EFFECTS WILL BE SECURELY MOUNTED OR IMMOBILIZED TO PREVENT UNINTENDED MOVEMENT OR MISALIGNMENT. BEAM LIMITS WILL BE PROVIDED AS AN INHERENT PART OF THE SYSTEM DESIGN TO PREVENT OVERFILLING OF SCREENS, BEAM STOPS, TARGETS,
- I. X LASER PROJECTORS WILL NOT BE DELIVERED TO ANY OTHER PARTY UNDER AN AGREEMENT OF SALE, LEASE, OR LOAN UNLESS AND UNTIL THE RECIPIENT DEMONSTRATES THAT THEY HAVE A VARIANCE IN EFFECT AT THE TIME OF DELIVERY THAT PERMITS THEM TO PRODUCE LASER LIGHT SHOWS INCORPORATING SUCH PROJECTOR.
- j. X IN ADDITION TO THE REQUIREMENTS OF 21 CFR 1040.10 (h), THE MANUFACTURER OF LASER PROJECTORS/SYSTEMS WILL PROVIDE TO PARTIES WHO PURCHASE, LEASE, OR BORROW THE EQUIPMENT, ADEQUATE USER'S INSTRUCTIONS FOR SAFE INSTALLATION AND OPERATION AND WHICH EXPLAIN THE RESPONSIBILITY OF THE RECIPIENT AS AN INDEPENDENT LIGHT SHOW MANUFACTURER TO SUBMIT THE REQUIRED REPORTS AND APPLY FOR AND OBTAIN A VARIANCE FROM CDRH PRIOR TO INTRODUCTION INTO COMMERCE OF ANY LASER LIGHT SHOWS.
- k. X THE REQUIREMENTS OF 21 CFR 1002.30 (a)(1) AND (2) WILL BE ACCOMPLISHED THROUGH THE USE OF WRITTEN PROCEDURES FOR SETUP ALIGNMENT, TESTING, AND PERFORMANCE OF EACH SHOW. THESE PROCEDURES WILL BE IN SUFFICIENT DETAIL TO ENSURE COMPLIANCE WITH 21 CFR 1040.10. THE CONDITIONS OF THIS VARIANCE, AND CONTROL OF ACCESS TO RADIATION AREAS USING THE PROCEDURES DESCRIBED IN THE ANSI Z136.1 STANDARD FOR THE SAFE USE OF LASERS (AMERICAN NATIONAL STANDARDS INSTITUTE, 1430 BROADWAY, NEW YORK, NY 10018) OR ANY OTHER EQUIVALENT USER CONSENSUS STANDARD AND AND, WHERE APPLICABLE, STATE OR LOCAL REQUIREMENTS. LASER RADIATION AREAS WHICH CAN CONTAIN RADIATION LEVELS ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c), WILL BE CLEARLY IDENTIFIED BY THE POSTING OF WARNING SIGNS AND/OR RESTRICTED ACCESS THROUGH PHYSICAL MEANS (SUCH AS PRESSURE SWITCHES, PHOTOCELLS, BARRIERS, GUARDS, ETC.). THESE REQUIREMENTS APPLY TO TEMPORARY AREAS (SUCH AS DURING SETUP AND ALIGNMENT PROCEDURES) AND TO FINAL OR PERMANENT AREAS. THE VARIANCE HOLDER WILL RETAIN THE RECORDS OF THESE PROCEDURES AND THE RESULTS OF ALL TESTS AS REQUIRED BY 21 CFR 1002.31, A COPY OF THE VARIANCE APPLICATION, THE APPROVAL LETTER, CURRENT PROCEDURES AND RECORDS RELATING TO EACH PARTICULAR SHOW WILL BE WITH THE OPERATOR OR OTHER RESPONSIBLE INDIVIDUAL AND WILL BE MADE AVAILABLE FOR INSPECTION BY FDA AND OTHER RESPONSIBLE AUTHORITIES

FORM FDA 3147 (3/87)

- I. X ADVANCE WRITTEN NOTIFICATION WILL BE MADE AS EARLY AS POSSIBLE TO APPROPRIATE FEDERAL, STATE AND LOCAL AUTHORITIES PROVIDING SHOW ITINERARY WITH DATES AND LOCATIONS CLEARLY AND COMPLETELY IDENTIFIED, AND A BASIC DESCRIPTION OF PROPOSED EFFECTS INCLUDING A STATEMENT OF THE MAXIMUM POWER OUTPUT INTENDED. SUCH NOTIFICATIONS WILL BE MADE, BUT NOT NECESSARILY LIMITED TO:
 - (1) THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF COMPLIANCE (HFZ-312),2098 GAITHER ROAD, ROCKVILLE, MD 20880.PROVIDING THE INITIAL AND CLOSING DATES FOR THE FIXED INSTALLATION AND THE ITINERARY FOR MOBILE SHOWS IN ADDITION, UNLESS ALL ASPECTS OF EACH SHOW HAVE BEEN REPORTED AND THE ACCESSION NUMBERS CLEARLY REFERENCED, EACH NOTICE WILL INCLUDE DETAILED DESCRIPTIONS OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE PERFORMED IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE REGULATIONS AND THIS VARIANCE.
 - (2) THE FEDERAL AVIATION ADMINISTRATION (FAA) FOR ANY PROJECTIONS INTO OPEN AIRSPACE AT ANY TIME (I.E., INCLUDING SET-UP, ALIGNMENT, REHEARSALS, PERFORMANCES, ETC.). IF THE FAA OBJECTS TO ANY LASER EFFECTS, THE OBJECTIONS WILL BE RESOLVED AND NY CONDITIONS REQUESTED BY FAA WILL BE ADHERED TO. IF THESE CONDITIONS CAN NOT BE MET. THE OBJECTIONABLE EFFECTS WILL BE DELETED FROM THE SHOW.
 - (3) STATE AND LOCAL RADIATION CONTROL OFFICES/AGENCIES FOR ALL SOWS TO BE PERFORMED WITHIN THEIR JURISDICTIONS. ALL REQUIREMENTS OF STATE AND LOCAL LAW WILL BE SATISFIED AND ANY OBJECTIONS RAISED BY LOCAL AUTHORITIES WILL BE RESOLVED OR THE EFFECTS DELETED. (LISTS OF FEDERAL AND STATE OFFICES ARE AVAILABLE FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH UPON REQUEST.)

14.	RE	MA	R	S

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading or incorrect in any material way. I have submitted/will submit all reports required by 21 CFR 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Bureau of Radiological Health to supply such other information that may be necessary to evaluate and act on this application.

15. SIGNATURE

16. NAME (Type or Print)

17. TITLE

Martin Zbosnic

President

MARCO VEGA MOBOLAZER INC 790 HAMPSHIRE RD STE D

SHIP DATE: 05Jan00 ACCOUNT #: 193442277 ACTUAL WGT: 1 LB

THOUSAND OAKS CA 91361
(805)230-2166
TO: ATTN: HEARING CLERK
FDA- FOOD DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
DOCKETS MGMT. BRANCH [HFA-305]
ROCKVILLE MD 20857 (301)594-4654

FedEx

4609 9762 8415

REF: CREATIVE ARTISTS PRODUCTIONS

EXPRESS SAVER PACKAGE

cad# 0618035

05Jan00 15:48

Deliver by: 10Jan00



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